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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N-0787]

Parke-Davis Pharmaceutical Research et al.; Withdrawal of
Approval of 14 New Drug Applications and 13 Abbreviated New Drug
Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing
approval of 14 new drug applications (NDA's) and 13 abbreviated
new drug applications (ANDA's). The holders of the applications
notified the agency in writing that the drug products were no
longer marketed and requested that the approval of the
applications be withdrawn.

EFFECTIVE DATE: (Insert date of publication in the FEDERAL
REGISTER.)

FOR FURTHER INFORMATION CONTACT:

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Center for Drug Evaluation and Research (HFD-7),
Food and Drug Administration,
5600 Fishers Lane,
Rockville, MD 20857,
301-594-2041.

SUPPLEMENTARY INFORMATION: The holders of the applications
listed in the table in this document have informed FDA that these
drug products are no longer marketed and have requested that FDA
withdraw approval of the applications. The applicants have also,
by their request, waived their opportunity for a hearing.

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NWL 1

Application No.	Drug	Applicant
NDA 3-402	Pitressin Tannate in Oil (Vasopressin Tannate), 5 Pressor Units, 1 milliliter	Parke-Davis Pharmaceutical Research, 2800 Plymouth Rd., Ann Arbor, MI 48105.
NDA 6-212	Propylthiouracil Tablets	Abbott Laboratories, 100 Abbott Park Rd., Abbott Park, IL 60064.
NDA 10-355	Quarzan (clindium bromide) Capsules	Hoffmann-LaRoche Inc., 340 Kingsland St., Nutley, NJ 07110-1199.
NDA 12-184	Norlutate (Norethindrone Acetate) 5-milligram (mg) Tablets	Parke-Davis Pharmaceuticals, 2800 Plymouth Rd., Ann Arbor, MI 48105.
NDA 12-470	Akrinol Cream	Schering-Plough Corp., 2000 Galloping Hill Rd., Kenilworth, NJ 07033.
NDA 13-294	Azo-Gantanol (sulfa- methoxazole and phenazo- pyridine hydrochloride) Tablets	Hoffmann-La Roche Inc.
NDA 16-020	Symmetrel (amantadine hydro- chloride) Capsules, 100 mg	Endo Pharmaceuticals, Inc., 500 Endo Blvd., Garden City, NY 11530.

Application No.	Drug	Applicant
NDA 16-191	Sorbitrate (isosorbide dinitrate) Sublingual Tablets, 2.5 and 5 mg	Zeneca Pharmaceuticals, a business unit of Zeneca, Inc., 1800 Concord Pike, P.O. Box 15437, Wilmington, DE 19850- 5437.
NDA 17-117	Symmetrel (amantadine hydro- chloride) Capsules	Endo Pharmaceuticals, Inc.
NDA 17-552	Tylenol Acetaminophen Extra Strength Tablets, 500 mg	McNeil Consumer Products Co., 7050 Camp Hill Rd., Fort Washington, PA 19034-2299.
NDA 18-179	Valrelease (diazepam) Capsules	Hoffman-LaRoche Inc.
NDA 50-345	Cordran N Ointment (flurandrenolide)	Lilly Research Laboratories.
NDA 50-346	Cordran N Cream (flurandrenolide)	Do.
NDA 50-379	Sterile Ophthalmic Solution Neo-Hydeltrasol (neomycin sulfate-prednisolone sodium phosphate ophthalmic solution)	Merck & Co., Inc., P.O. Box 4, BLA-20, West Point, PA 19486.
ANDA 62-385	Neomycin Sulfate Powder, USP (for compounding oral products)	Paddock Laboratories, Inc., 3940 Quebec Ave. North, Minneapolis, MN 55427.
ANDA 62-455	Polymyxin B Sulfate, USP (for prescription compounding)	Do.

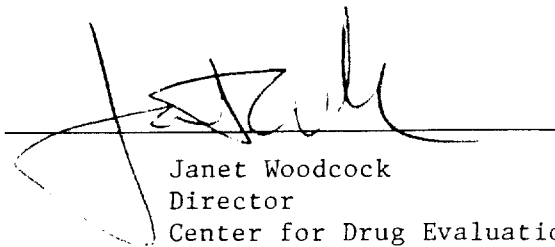
Application No.	Drug	Applicant
ANDA 62-456	Bacitracin Powder, USP (for prescription compounding)	Do.
ANDA 74-084	Diltiazem Hydrochloride Tablets USP, 30 mg and 60 mg	Novopharm N.C., Inc., agent for Novopharm Ltd., 4700 Novopharm Blvd., Wilson, NC 27893.
ANDA 74-511	SULSTER (Sulfacetamide Sodium and Prednisolone Sodium Phosphate Ophthalmic Solution, 10%/eq. 0.23% phosphate)	Taylor Pharmaceuticals (an Akorn Co.), 150 South Wyckles Rd., P.O. Box 1220, Decatur, IL 62525- 1220.
ANDA 80-025	Sulf-10 (Sulfacetamide Sodium Ophthalmic Solution, USP) 10%	Ciba Vision, 11460 Johns Creek Pkwy., Duluth, GA 30097-1556.
ANDA 83-648	Mepro tabs (Meprobamate Tablets USP, 400 mg)	Wallace Laboratories, Division of Carter- Wallace, Inc., Half Acre Rd., P.O. Box 1001, Cranberry, NJ 08512- 0181.
ANDA 85-136	Methocarbamol Tablets USP (750 mg)	Forest Laboratories, Inc., 909 Third Ave., New York, NY 10022- 4731.
ANDA 85-137	Methocarbamaol Tablets USP (500 mg)	Inwood Laboratories, Inc., 909 Third Ave., New York, NY 10022- 4731.

Application No.	Drug	Applicant
ANDA 86-228	Nitroglycerin Extended- release Capsules (2.5 mg)	Geneva Pharmaceuticals, Inc., 2655 West Midway Blvd., P.O. Box 446, Broomfield, CO 80038-0446.
ANDA 86-230	Nitroglycerin Extended- release Capsules (6.5 mg)	Do.
ANDA 87-797	Triamcinolone Acetonide Cream USP, 0.025%	Alpharma USPD, Inc., 333 Cassell Dr., suite 3500, Baltimore, MD 21224.
ANDA 88-220	Nitroglycerin Extended- release Capsules (9 mg)	Geneva Pharmaceuticals, Inc.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.82), approval of the applications listed in the table in this

document, and all amendments and supplements thereto, is hereby withdrawn, effective (insert date of publication in the FEDERAL REGISTER).

Dated: September 14, 1998



Janet Woodcock
Director
Center for Drug Evaluation and Research

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